

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

PB60330US

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Signature _____

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Application Number

10/561,498

Filed

December 19, 2005

First Named Inventor

LIDDLE, John

Art Unit

1612

Examiner

OAZI, Sabiha Naim

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

/Kathryn L. Coulter/

Signature

☐ assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96)

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Registration number if acting under 37 CFR 1.34 _____

April 8, 2010

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : LIDDLE, John
Filing No. : 10/561,498
Filing Date : December 19, 2005
Title : *Substituted Diketopiperazines as Oxytocin Antagonists*

Group / Art Unit : 1612
Examiner : QAZI, Sabiha Naim

Confirmation No. : 6334

Docket No. : PB60330US

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW-REMARKS

Pending claims 1-4, 7, and 9-11 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,514,437. This request for pre-appeal review is in response to the current Final Office Action mailed December 10, 2009. Also filed herewith are a Notice of Appeal and a Request for Pre-Appeal Brief Review. Applicants respectfully request review by a Pre-Appeal Panel in light of the following remarks.

The Examiner states that claims 1-4, 7, and 9-11 are *prima facie* obvious over claims 1-12 of U.S. Patent No. 7,514,437 ('437) because the compounds recited in the present application fall within the scope of claims 1-12 of '437. Firstly, it is noted that the compounds recited in claims 1-4, 7, and 9-11 of the present application do not fall within the scope of claims 5, 7, or 10 of the '437 patent. Secondly, a *prima facie* case of double patenting cannot be established merely by demonstrating that the claims of a pending patent application fall within the scope of the claims of a commonly-owned patent. The *Manual of Patent Examining Procedure (MPEP)* states:

Domination and double patenting should not be confused. They are two separate issues. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application. Domination by itself, i.e.,

in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection.

MPEP § 804, citing *In re Kaplan*, 789 F.2d 1574, 1577-78, 229 USPQ 678, 681 (Fed. Cir. 1986); and *In re Sarrett*, 327 F.2d 1005, 1014-15, 140 USPQ 474, 482 (CCPA 1964). Thus, while it is true that claims 1-4, 6, 8, 9, 11, and 12 of U.S. Patent No. '437 dominate claims 1-4, 7, and 9-11 of the present patent application, this is insufficient to support a double patenting rejection.

In the Final Office Action, the Examiner states that "[T]he instant claimed compounds would have been obvious because one of skill in the art would have been motivated to prepare compounds embraced by the genus of the above cited references with the expectation of obtaining beneficial compounds." Office Action dated December 10, 2009, page 5, paragraph 2. However, the Office Action does not provide any reasoning or rationale to support the statement that the claims of the '437 patent would direct one of ordinary skill in the art to make the specific compounds claimed in the present application.

According to the Supreme Court, in order to establish a *prima facie* case of obviousness, it must be shown that there is "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). In the present case, the Examiner argues that it would be *prima facie* obvious to modify the compounds recited in claims 1-12 of U.S. Patent No. 7,514,437 to produce the compounds recited in the claims of the present application. However, the claims of the '437 patent encompass a very large genus of compounds, and the Examiner has not articulated any reason that one of skill in the art would have been motivated to (1) select any one particular compound from the many different compounds listed by the claims of this patent and then (2) modify this compound to produce a compound having the specific combination of substituents recited in the narrow claims of the present application. As no such reason has been identified, a *prima facie* case of obviousness has not been established and the rejection should be withdrawn.

Finally, the Examiner states "[I]t has been decided by Courts that the indiscriminate selection of 'some' among the 'many' is considered *prima facie* obvious."

Office Action dated December 10, 2009, page 5, paragraph 1. However, this statement is not relevant to the patentability of the claims of the present application, because the compounds encompassed by the present claims were not selected indiscriminately. As noted on page 7-8 of Applicant's Amendment and Response dated September 25, 2009, the compound recited in claim 2 was selected based on its advantageous pharmacokinetic profile. The claims of the '437 patent provide no suggestion that a compound as recited in the claims of the present application would have the advantageous pharmacokinetic profile as described in Liddle *et al.* (2008) *Bioorg Med Chem Lett.* 18(1):90-4.

In conclusion, the Final Office Action fails to provide all the elements required for a *prima facie* showing of nonstatutory obviousness-type double patenting because the Examiner has not identified a reason why a person of ordinary skill in the art would combine the elements recited in claims 1-12 of U.S. Patent No. 7,514,437 to produce the compounds claimed in claims 1-4, 7, and 9-11 of the present application. Accordingly, the rejection of the pending claims for nonstatutory obviousness-type double patenting should be withdrawn. Applicants request that the panel grant this relief.

Respectfully submitted,

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